

Inventor: Ruoslahti et al.
Serial No.: 09/765,086
Filed: January 17, 2001
Page 4

REMARKS

Prior to entry of the present amendments, claims 8 to 17 and 23 to 27 were pending. Claims 10 to 12, 15 to 17 and 25 to 27 have been canceled herein. Thus, claims 8, 9, 13, 14, 23 and 24 are pending and presently under examination.

Regarding the Declaration under 37 C.F.R. 1.131

The Office Action indicates that the Declaration filed on June 5, 2003, under 37 C.F.R. 1.131 must be perfected in order to overcome the Ellerby et al. reference. Firstly, the Office Action indicates that the Declaration shows evidence of conception or reduction to practice of only parts of the claimed subject matter. In particular, the structure in the attached proposal (Exhibit 1) appears to be SMSIARL-GG-(KLAKLAK)₂, not SMSIARL-GG-D(KLAKLAK)₂, as in dependent claims 11, 12, 16 and 17. However, Applicants have canceled herein dependent claims 11, 12, 16, 17, 23 and 24, and further note that the peptide SMSIARL-GG-(KLAKLAK)₂ is encompassed within the chimeric prostate-homing pro-apoptotic peptide of pending claims 8, 9, 13, 14, 23 and 24. Thus, the Declaration shows evidence of conception and reduction to practice of the subject matter now pending. Secondly, the Declaration has been perfected to indicate that conception or reduction to practice was by the inventive entity, namely, the five inventors. In view of the above remarks, Applicants respectfully request that the Examiner reconsider the perfected Rule 131 Declaration attached hereto.

Regarding the §103 rejection of claims 8 to 17 and 23 to 27

The rejection of claims 8 to 17 and 23 to 27 under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/46284 and Ellerby et al. in view of Arap et al. is respectfully traversed. The Office Action indicates that WO 99/46284 describes peptides that bind to the prostate but acknowledges that this publication does not describe an anti-microbial peptide. Ellerby et al. allegedly report the p(KLAKLAK)_2 antimicrobial peptide and the "GG" coupling domain and further report that directing an antimicrobial peptide to angiogenic endothelial cells results in anti-cancer activity. Furthermore, the Examiner asserts that one skilled in the art would have been motivated to direct an anti-cancer agent to non-cancerous cells given that the mutation rate of non-malignant cells is expected to be lower than that of malignant cells as suggested in Arap et al. In view of the cancellation of claims 10 to 12, 15 to 17 and 25 to 27, Applicants address this rejection as it pertains to pending claims 8, 9, 13, 14, 23 and 24.

Applicants submit that the cited reference by Ellerby et al. is not prior art with respect to the claimed invention because Applicants reduced the invention to practice prior to September of 1999, when Ellerby et al. was published. In this regard, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 signed by the five named inventors of the subject application, along with copies of relevant documentary evidence of Applicants' date of invention. The dates on the documentary evidence have been redacted; however, the dates shown in the

original documents indicate that Applicants had obtained a chimeric prostate-homing pro-apoptotic peptide and, further, had demonstrated selective cell death in prostate tissue prior to September of 1999. In sum, the Ellerby et al. reference was not published more than one year prior to the priority date of the above-identified application (January 21, 2000), and, furthermore, was not published before Applicants reduced the invention to practice. Thus, the cited reference by Ellerby et al. is not prior art with respect to the claimed invention.

Applicants submit that, prior to the present invention, there was no teaching or suggestion of an antimicrobial peptide as part of a chimeric peptide together with a prostate-homing peptide. At best, antimicrobial peptides had been used alone as anti-bacterial agents or suggested to be useful alone in lysing cancer cells. Specifically, WO 99/46284 reports peptides that bind to prostate tissue but does not teach or suggest chimeric peptides which include an antimicrobial peptide linked to a prostate-homing peptide. Arap et al. report conjugates containing doxorubicin and tumor homing peptides yet do not teach or suggest chimeric peptides that contain an antimicrobial peptide component. In sum, as discussed above, the cited reference by Ellerby et al. is not prior art with respect to the claimed invention, and the remaining references (WO 99/46284 and Arap et al.), neither alone nor in combination, teach or suggest a chimeric peptide composed of an antimicrobial peptide linked to a prostate-homing peptide.

Inventor: Ruoslahti et al.
Serial No.: 09/765,086
Filed: January 17, 2001
Page 7

In view of the above remarks and the Declaration under 37 C.F.R. §1.131 submitted herewith, Applicants respectfully request that the Examiner remove the rejection of claims 8, 9, 13, 14, 23 and 24 under 35 U.S.C. § 103.

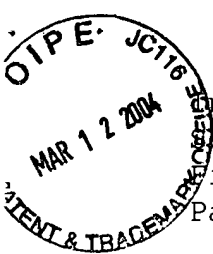
Provisional double patenting rejection of claims 12, 17 and

26

The provisional objection to claims 12, 17 and 26 as being substantial duplicates of claims 11, 16 and 25 is respectfully traversed.

Applicants respectfully submit that claims 12, 17 and 26 are patentable as written, and that the scope of each of these claims is narrower than the scope of claims 11, 16 and 25, respectively. In particular, the chimeric peptide recited in claim 12 is SMSIARL-GG-D(KLAKLAK)₂, while the subject matter of claim 11 "comprises" the sequence SMSIARL-GG-D(KLAKLAK)₂ and, therefore, encompasses chimeric peptides which include the recited "SMSIARL-GG-D(KLAKLAK)₂" sequence as part of a larger sequence. Similarly, claim 16 is broader than claim 17 due to the open language of claim 16 indicating that the recited chimeric peptide "comprises" the sequence SMSIARL-GG-D(KLAKLAK)₂. Finally, claim 25 is broader than claim 26 due to the open language of claim 25. Thus, the scope of each of these claims is distinct.

Nevertheless, claims 12, 17 and 26 have been canceled herein in order to further prosecution of the subject application, without prejudice to Applicants pursuing these claims in a continuation application claiming the benefit of



Inventor: Ruoslahti et al.
Serial No.: 09/765,086
Filed: January 17, 2001
Page 8

priority of the subject application. In view of the above remarks and amendments, Applicants respectfully request that the Examiner remove the provisional double patenting rejection of claims 12, 17 and 26.

CONCLUSION

Applicant respectfully requests that the Examiner consider the remarks made above. Should the Examiner have any questions, he is invited to call the undersigned agent or Cathryn Campbell.

Respectfully submitted,

Date: March 12, 2004

Andrea L. Gashler
Andrea L. Gashler
Registration No. 41,029
Telephone: (858) 535-9001
Facsimile: (858) 535-8949

McDERMOTT, WILL & EMERY
4370 La Jolla Village Drive
Suite 700
San Diego, California 92122